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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,251	04/05/2007	Fabrizio Dolfi	29048SUS0X PCT	2049

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
04/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,251	DOLFI ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed January 28, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 27 have been amended.

2. Claims 1-31 are pending in the case.

3. Claims 16-31 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Response to Arguments

6. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description in regards to the term "cosmetic active agent"

Applicant's arguments filed 1/28/2010 have been fully considered but they are not persuasive. Applicant asserts that the term is known in the art and cites Kirk-Othmer as a reference that there are known skin care products recognized as cosmetic actives. This not persuasive as Kirk-Othmer recite conditioners (e.g. humectants), moisturizers, and sunscreens, that Applicant is arguing to be cosmetic actives but are currently recited in the claims and are addressed to be distinct from the grouping which goes to the issue of written description and indefiniteness as addressed previously. It is also noted that Kirk-Othmer addresses skin care products such as baby preparations (e.g. 9.1 table) which are product preparation forms, not cosmetic active agents which are

recited by the claims as the cosmetic active is an additive to the preparation, not the preparation form. There are also no structural identifying characteristics for the actives/compounds recited.

Accordingly, the rejection is maintained.

7. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in regards to the term "skin calmative and protective agents".

Applicant's arguments filed 1/28/2010 have been fully considered but they are not persuasive. Applicant asserts that the term is known in the art and cites the specification Page 6 addressing skin calmative and protective agents such as allantoin as support for written description. This not persuasive as the claims are directed to a compound defined by reference to desirable characteristics or properties, whereas the application provides support for only one compound within the scope of what is claimed. There is no evidence that there is any per se structure/function relationship and a single disclosed compound is not a representative number of compounds to support written description for the generic recitation in the absence of sufficient recitation of distinguishing identifying characteristics. Therefore, the claimed invention is not supported by adequate written description.

Accordingly, the rejection is maintained.

8. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in regards to the term "pro-penetrating agents".

Applicant's arguments filed 1/28/2010 have been fully considered but they are not persuasive. Applicant cites a section of U.S. 7316810 which defines a specific formula for propenetrating agents and asserts that it fulfills Applicant's written description requirement. This not persuasive as fulfilled written description in a unrelated and different application/patent with the definition for a specific formula for propenetrating agents does not preclude Applicant's burden to fulfill their own written description for what is encompassed by the term. The referenced Patent is not even related to the instant application continuity data and does not provide written description for the claimed term.

Accordingly, the rejection is maintained.

9. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in regards to "antiproliferative agent". Applicant's arguments filed 1/28/2010 have been fully considered but they are not persuasive. Applicant argues that anti-proliferative drugs are for chemotherapy and recites alkylating, antibiotic, and hormones for chemotherapy as antiproliferative agents. This not persuasive as the specification does not describe antiproliferative agents to be for chemotherapy and there is no description for what compounds would be encompassed by the term. It is noted that it is well known in the art that many conditions are related to proliferation and a general search cited pulmonary hypertension, retinopathy, and neovascular glaucoma which is not consistent with Applicant's arguments and is confusing which goes to the issues of written description and indefiniteness.

Accordingly, the rejection is maintained.

10. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the term "cosmetic active agent" wherein it is unclear what materials would constitute a "cosmetic active agent". There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection is maintained.

11. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the term "skin calmative and protective agents" wherein it is unclear what materials would constitute a "skin calmative and protective agents". There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection is maintained.

12. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the term "pro-penetrating agents". There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection is maintained.

13. Claim 16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkin et al. (WO 02/074290) in view of Bannwarth et al. (Tissue and systemic diffusion of idrocilamide after cutaneous administration).

Applicant's arguments filed 1/28/2010 have been fully considered but they are not persuasive. Applicant's arguments center on the assertion that the chemical

structure of idrocilamide does not fall in the non-steroidal anti-inflammatory drugs of Arkin listing several arylpropionic acids. This is not persuasive as Applicant cites idrocilamide is known to be an arylpropionic acid NSAID in the instant specification (see Pate 3 of specification). If Applicant is asserting that idrocilamide is not an arylpropionic acid NSAID, Applicant is arguing the teaching of their own specification and questioning the validity of the instant specification. It is unclear what Applicant is attempting to address.

Applicant's argument of case law it is not persuasive as the merits of the cases are not the same as those in the instant case and prosecution of previous cases have no bearing on the instant case as each application is to be treated on its own merits.

In regards to Applicant's assertion that Bannwarth does not state the relative performance of idrocilamide with diclofenac to be considered functionally equivalent, this is not persuasive as Bannwarth explicitly states that idrocilamide is an effective anti-inflammatory and that its cutaneous application gave a similar observed result found with diclofenac gel wherein to two known antiinflammatories which are used for the same purpose are functionally equivalent, and it would be obvious to use one functionally equivalent anti-inflammatory for another.

As for Applicant's assertion in Bannwarth's description of the passage of idrocilamide through the dermal layer is of teaching away for inflammatory dermatitis. This is not persuasive as the claim is for rosacea and not inflammatory dermatitis. It is also noted that penetration through the dermal layer is desirable as rosacea

presentation are also found in the deep dermis and subcutis (see Aroni et al.-Rosacea: A Clinicopathological Approach)

Accordingly, the rejection is maintained.

Conclusion

14. Claims 16-31 are rejected.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612